Seize the day, . . . s(e)ize the device: the emerging imaging modality to improve left atrial appendage device sizing

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Abstract

There is still uncertainity about the use of CT-scan for LAAO device sizing. The main reason for this disappointing position is likely to relate to the scarcity of robust data, since there is still difference among institutions with regards how to perform measurement of the devices. Dallan et al. (1) report their own experience on the use of a novel computed tomography angiography-based (CTA) for sizing the Watchman Flex device for left atrial appendage occlusion (LAAO) . The authors through the TruPlan software package that a pre-procedural CTA sizing protocol can be applied successfully with ICE guidance and provide excellent procedural outcomes.The applied CTA protocol is safe and can provide high success rates with the WatchmanTM FLX device reducing the number of deployment attempts and reducing the risk of complications.

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In this issue of the Journal, Dallan et al. (1) report their own experience on the use of a novel computed tomography angiography-based (CTA) for sizing the Watchman Flex device for left atrial appendage occlusion (LAAO) . The authors have tested the TruPlan software package for the methodology and investigated if it can reduce the number of device deployment and the risk of complications. The principal results of the study were: 1) A pre-procedural CTA sizing protocol can be applied successfully with ICE guidance

and provide excellent procedural outcomes; 2) CTA protocol is safe and can provide high success rates with the WatchmanTM FLX device reducing the number of deployment attempts and reducing the risk of complications.

Among 136 patients evaluated, pre-procedural CT imaging accurately predicted the size of the device in 91% of patients. Only in ten patients a new sized device was required and in 2 patients were aborted. The authors conclude that the CTA-based pre-procedural sizing methodology for Watchman Flex occluder is safe, feasible and provide appropriate device identification with an excellent clinical outcome.

Technology concept

Needless to highlight that adequate pre-procedural planning, intraprocedural imaging is of great importance throughout all phases of the implantation procedure for LAAO, especially for evaluation of the left atrial appendage (LAA) anatomy and guidance of device implantation. Intraprocedural imaging is critical to rule out thrombus, re-assess size of the LAA ostium, landing zone, length, number of lobes and shape. Furthermore, imaging is pivotal in guiding trans-septal puncture within a specific region of the fossa ovalis, sheath placement, device placement, and assessment of device stability, post-placement leak evaluation and procedural complications. Despite technology evolution, angiography remains an important intraprocedural step, but it alone has several limitations for detailed guidance of LAAO. Then, transesophageal echocardiography (TEE) has been the gold standard imaging modality for LAAO since most interventional cardiologists are familiar with technique. It provides high definition images of the right and left atrium, interatrial septum and LAA anatomy. In addition, modern TEE technology provides reliable 3D imaging. Nevertheless, important limitations exist such as the need for general anesthesia or conscious sedation, contraindications to TEE (such as esophageal varices), a dedicated TEE operator as well as interference with fluoroscopy. This has recently led to the use of Intracardiac echocardiography (ICE) as an alternative to TEE for guiding LAAO (2,3). Recent data show that ICE is non-inferior to TEE for guiding LAA occlusion procedures in terms of procedural success, peri-procedural complications and embolic events at follow-up (4,5). A recent meta-analysis including a total of 1,122 patients confirmed similar procedural success rate with a trend for less procedure-related complications in the ICE group and lower volume of contrast media used in the ICE group (6)

The Role of CT-scan

Over the years, several discussions about the use of CT-scan for LAA occluder device sizing have been raised by investigators, leading to non-homogeneous conclusions. The main reason for this disappointing position is likely to relate to the scarcity of robust data, since there is still difference among institutions with regards how to perform measurement of the devices. In several institutions, the pre-procedural device sizing is guaranteed by TEE carried out at the same time of thrombus evaluation in LAA. Therefore, even for the workflow's sake, CT-scan is no strictly required and the procedure itself relies on sizing obtained by fluoroscopy and TEE in real time during the procedure.

One could raise the question whether pre-procedural CT-scan is critical for identifying the right device sizing and, thus if it should become the standard approach for LAA closure. Based on the preliminary data offered by Dallan and co-workers, it seems that the novel TruPlan software accurately provides the size of device and it might also improve the patient's workflow in the lab. Moreover, they did not observe device embolization, nor strokes or any other major complications. The CT sizing strategy adopted by the authors was associated with only 1.04 devices used per patient. Furthermore, this approach yielded a 99% procedural success and 99% closure rate at 45-day follow up which compares with previous clinical outcome reported with TEE (7,8). In other words, the CT sizing through the TruPlan software does not negatively affect the outcome of Watchman Flex device. Actually, based on these results, very comparable to the current use of intraprocedural TEE and/or ICE, the operators have their own choices of how to perform LAAO intervention. Then, which is the real novelty for the physicians provided by the TruPlan software? First, the methodology of LAA measurements based on an area-derived diameter as opposed to the maximum diameter currently offered by CT technique provides a more adequate device sizing thus, reducing the likelihood of

device over-compression. In fact, sizing and compression estimates are derived automatically, and device selection can be chosen based on area-derived diameter. Moreover, it seems even more crucial the role of the TruPlan software in selecting the most adequate device when two device sizes fit within the recommended 10-30% compression range. Under these circumstances, the algorithm would select a larger device at higher compression if accommodated by appendage depth. Once selected, TruPlanTM digitally superimposes the device onto the CT image of the appendage. The device overlay feature is certainly a key element in decision-making, to assess adequacy of fit. Then, the device can be virtually repositioned in the appendage to predict how appendage tissue might interact with the device upon implant. Interestingly, the program simulates device shape at any predicted compression, forecasting how the device will appear fluoroscopically in the appendage.

Is pre-procedural CT TruPlan-based reasonably enough?

The authors have performed LAAO by using ICE to guide transseptal puncture and view the LAA from the left atrium. The use of ICE favors a smoother intraprocedural workflow, since general anesthesia is not required and the operator can easily maneuver the ICE probe with no need of the echo expert's assistance. In our own experience, LAA visualization and measurements, ruling out thrombus, device sizing and placement can effectively achieved through ICE and with an excellent outcome (9). Also, with the advent of 3-D ICE technology (10), more reliable and adequate measurements is offered guiding to a successful and safe LAAO procedure . Unfortunately, in this prospective study there is no data comparing the pre-procedural CT information obtained through the TruPlan software with that produced by intraprocedural ICE. The demonstration that device selection provided by pre-procedural CT-scan TruPlan software based consistently coincides with the device sizing obtained by intraprocedural ICE measurements, would have reinforced the significance of this novel pre-procedural CT methodology. Furthermore, no direct comparison was made in randomizing fashion with other CT-scan sizing methodologies.

The Cost Benefit Ratio

From an economical point of view, the additional costs of the implementation of the novel TruPlan software should be taken into account in the whole workflow process of LAAO. This should be offset by the savings obtained from shorter cath-lab times, if the operator already knows the device sizing beforehand, then confirmed by intraprocedural ICE measurements, and from reduction in the clinical team needed for the procedure.

Needless to highlight that the data of this prospective single-center study need to be corroborated by multi-center experience and, more importantly this methodology should be implemented for other device platforms.

Anyhow, we acknowledge and praise the authors' efforts to identify a more sophisticated and reliable methodology for the improvement of LAAO device sizing through a novel pre-procedural CT evaluation. The results of this study represents an important step forward in our understanding of which imaging process is more favorable for the improvement of LAAO. We all hope this could make the LAAO workflow smoother, safer and cost beneficial in the very near future.

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